IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

EARL RINGO, et al.,	)	
Plaintiffs,	)	
	)	
vs.	)	**No. 09-4095-CV-C-NKL**
	)	
GEORGE A. LOMBARDI, et al.,	)	
Defendants.	)	

Reply Suggestions in Support of Plaintiffs' Motion for Summary Judgment

On August 19, 2010, the Court denied Defendants' motion for judgment on the pleadings with respect to Plaintiffs' preemption claims. ECF Doc. 138, at 7-11. The Court ruled that Plaintiffs lack a private right of action under the Controlled Substances Act and the Food, Drug, and Cosmetic Act, but that a preemption claim does not require such a right of action. *Id.* at 7-10. The Court described the "open question" that would govern the merits of this case: *not* whether the preemption doctrine applies, but rather, whether the State's execution method "can consistently stand together with the CSA and FDCA." *Id.* at 11.

Devoting little attention to the Court's "open question," Defendants recycle the same arguments that a preemption theory is simply not available, or that the statutes simply don't apply. *But see* Order of Nov. 30, 2010 (Doc. 167) (on motion to amend complaint), at 4 ("[T]he Court does not entertain here arguments by Defendants that appear to relitigate whether Plaintiffs' complaint states a claim for preemption; the Court has held that it does."); Order of Aug. 19, 2010 (Doc. 138), at 10 ("On Defendants' amended motion to dismiss, the Court rejected Defendants' argument that the CSA and FDCA should not be considered in this case because they were not intended to address lethal injection situations."). Defendants are free to disagree with the Court's previous rulings, but their arguments are no more persuasive now than before.

The answer to the "open question" is now clear: the record shows that it is impossible to comply with both the State's execution method and federal law. Among other fixed

inconsistencies, Defendants assign to non-medical personnel the task of performing an "IV push" of the controlled substance sodium thiopental, in order to suppress pain – and yet federal law requires that this drug be administered by a federally licensed practitioner. *See* Plaintiffs' SOF ¶¶ 26-29, 58-61; 21 U.S.C. § 822(a)(2) (no dispensing without registration); 21 U.S.C. § 802(10) (term "dispense" includes "administering of a controlled substance"). Another stark inconsistency is that the protocol *requires* the use of thiopental regardless of whether this choice accords with a medical practitioner's judgment, reflected in a valid and statutorily-required prescription, that it optimally reduces the risk of excruciating pain from the other two drugs. *See* Plaintiffs' Ex. 5 (Depo. of M3) (also Defendants' Ex. 2), at 39 ("There's other things that can be used that are better drugs, but they're not part of the protocol that is used now."); Plaintiffs' SOF ¶¶ 16, 17, 56, 57; 21 U.S.C. § 353(b)(1) (requiring prescription); 21 U.S.C. § 829(b) (same).

Preemption exists "where compliance with both federal and state law is impossible, or where the state law is an obstacle to the accomplishment and execution of congressional purposes and objectives." Order of Aug. 19, 2010 (ECF Doc. 138), at 7-8, citing *Mensing v. Wyeth*, 588 F.3d 602 (8th Cir. 2009); *Lankford v. Sherman*, 451 F.3d 496, 510 (8th Cir. 2006). The undisputed facts show preemption here: it is physically impossible for Defendants to follow both their execution method and federal law, and furthermore, Defendants' chosen method stands as an obstacle to the "core" congressional purpose of ensuring that a "drug" is "safe and effective for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Either or both of these showings entitle Plaintiffs to judgment and appropriate equitable relief.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

FEDERAL CASES

STATE CASES

FEDERAL STATUTES

COURT RULES

STATE STATUTES

STATE REGULATIONS

OTHER AUTHORITIES

REPLY TO DEFENDANT'S RESPONSE TO PLAINTIFFS' UNCONTROVERTED MATERIAL FACTS

Defendants' factual assertions do not undermine Plaintiffs' entitlement to summary judgment. The matters purportedly "controverted" by Defendants either misrepresent the record, are not supported by record evidence as required by Rule 56(c) and Local Rule 56.1(a), or depart from Plaintiffs' factual statements in ways that are not remotely "material" so as to preclude summary judgment. These failings are detailed below:

SOF ¶ 8 (also ¶¶ 71, 73, 74) – Defendants controvert the assertion that M2 is not medically qualified to administer sodium thiopental, pancuronium bromide, or potassium chloride, based on M2's admission to that effect. *See* ECF Doc. 242, at 6, 12. Defendants seem to disagree with M2's legal conclusion but produce no evidence to refute M2's factual testimony that, because of the limitations on his licensure as he understands them, he would resign from the execution team rather than carry out the task of administering the lethal injection drugs. *See* Plaintiffs' Ex. 3 (also Defendants' Ex. 1) (M2 Depo.), at 162-63. Neither do Defendants attempt to show that Missouri's nursing laws differ from M2's understanding of them. *See* 20 Mo. CSR § 2200-6.030(7)(G) ("Graduate practical nurses and licensed practical nurses shall NOT, under any condition . . . [a]dminister drug(s) via the intravenous push or intravenous bolus mode of delivery except when life-threatening circumstances require such administration.")

SOF ¶ 13 – Defendants have not effectively controverted Plaintiffs' showing that non-medical personnel NM1 and NM2 lack medical training. Defendants acknowledge that Tom Clements and George Lombardi state that they are unaware of any such medical training. *See* ECF Doc. 242, at 6-7. Mr. Clements, in his capacity as the DOC's Director of Adult Institutions, was responsible for hiring the members the execution team. *See* Plaintiffs' Ex. 1 (also Defendants' Ex. 7) (Lombardi Depo.), at 56. Mr. Clements' inability to recall any medical

training of NM1 and NM2 creates the inference that NM1 and NM2 lack such training. Defendants present no admissible evidence to refute that inference. Defendants cite anesthesiologist M3's statement, in deposition, that one of the non-medical persons served as a "Med-Act" in the Army. *See* Plaintiffs' Ex. 5 (also Defendants' Ex. 2) (M3 Depo.), at 94. But M3's statement is hearsay and does not describe what training, if any, the non-medical executioner had. *See* Fed. R. Civ. P. 56(c)(2). For that matter, Defendants were specifically asked, during discovery, to reveal the medical credentials of any members of the execution team. *See* Plaintiffs' Ex. 9 (request for production of documents), at 6 ¶ 12. No such credentials of NM1 or NM2 have been produced to Plaintiffs or the Court. For all of these reasons, Defendants have failed to present any evidence in support of their contention that either NM1 or NM2 is medically trained. Thus, Plaintiffs' SOF ¶ 13 must be taken as established for purposes of summary judgment. *See* Local Rule 56.1(a); *United States v. United States Currency in the Amount of $15,426.00*, No. 06-0862-CV-W-FJG, 2008 WL 4816984, at *1 n.1 (W.D. Mo. Oct. 31, 2008); *Lewis v. Police Officer Vidal*, No. 06-00036-CV-W-SWH, 2007 WL 2422877, at *3 n.14 (W.D. Mo. Aug. 21, 2007).

SOF ¶ 17 – Defendants proffer the factual "addition" that sodium thiopental is "itself lethal" in the dosage given during an execution. *See* ECF Doc. 242, at 7. In fact, anesthesiologist M3 testified that it is possible for such a dosage not to be fatal. Plaintiffs' Ex. 5 (also Defendants' Ex. 2) (M3 Depo.), at 72-73.

SOF ¶ 18 – M3 explained that, by paralyzing the patient with pancuronium bromide, he could provide a "smooth operation" that would not be "visually upsetting." Plaintiffs' Ex. 5 (also Defendants' Ex. 2) (M3 Depo.), at 75. Defendants complain that M3 was "speculating" as to why other officials have decided to include pancuronium within the set of lethal injection

drugs. *See* ECF Doc. 242, at 7. We need not bicker over whether M3 knows his superiors' motives for using the drug, because Defendants have explained it themselves in previous litigation:

> The injection of pancuronium bromide will cause complete paralysis within a few minutes. The pancuronium bromide will prevent seizure activity during an execution and thereby result in a more peaceful and dignified death.

Taylor v. Crawford, Eighth Circuit Case No. 06-3651, Appellants' Brief, at 20, available at 2006 WL 3857886 (record citations omitted); *see also Clemons v. Crawford*, 585 F.3d 1119, 1123 (8th Cir. 2009) (stating that pancuronium bromide "render[s] the prisoner unable to move").[1]

SOF ¶ 26 – The language of Defendants' "explanation" is ambiguous, and it should be clarified that the syringes are inserted into the IV port by the non-medical personnel rather than the physician. *See* Plaintiffs' SOF ¶ 27, which is uncontroverted.

SOF ¶¶ 34-35 – Defendants cannot seriously dispute that pancuronium bromide and potassium chloride would cause a prisoner to suffer excruciating pain if the prisoner is not first anesthetized. *See Baze v. Rees*, 553 U.S. 35, 53 (2008) ("It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride."); *Taylor v. Crawford*, 487 F.3d 1072, 1082 (8th Cir. 2007); *see also* Plaintiffs' Opposition Exhibit D (Heath Affidavit), at 3. Defendants present no evidence to dispute this established proposition, and no argument that a trial is necessary on this or any other issue.

SOF ¶ 36 – Again, M3 himself testified that it is possible for the given dose of thiopental

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[1]This is not the first time during this litigation that Defendants have played fast-and-loose with the purposes of Missouri's execution drugs. *See* Order of March 2, 2010 (Doc. 72), at 16-17.

not to be lethal. Plaintiffs' Ex. 5 (also Defendants' Ex. 2) (M3 Depo.), at 72-73.

SOF ¶ 39 – Defendants fail in their attempt to controvert defendant M3's own testimony that he is the prisoner's "doctor" on execution night. *See* ECF Doc. 242, at 9. The point is not that pancuronium bromide and potassium chloride are administered for a medical purpose, but rather, that M3 otherwise undertakes medical measures to reduce the risk that the prisoner will suffer pain. One of those measures is the administration of drugs, including the sedation of the prisoner with sodium thiopental. *See* Plaintiffs' Ex. 5 (also Defendants' Ex. 2) (M3 Depo.), at 112 ("administering drugs"). M3 also testified that the purpose of thiopental is to prevent pain by making the prisoner unconscious. *Id.* at 54-55, 58. But whatever M3's opinion, Defendants themselves are on record that the purpose of thiopental is to make an execution "humane." *See* Order of March 2, 2010 (Doc. 72), at 17, and sources cited.

SOF ¶ 40 – Defendants controvert this statement because it is not contained within page 152 of nurse M2's deposition. *See* ECF Doc. 242, at 9. In fact, the statement is contained within page 151 of the deposition. *See* Plaintiffs' Ex. 3 (also Defendants' Ex. 1), at 151. Plaintiffs apologize for this error.

SOF ¶ 44 – Defendants are bound by their Answer. "[E]ven if the post-pleading evidence conflicts with the evidence in the pleadings, admissions in the pleadings are binding on the parties and may support summary judgment against the party making such admissions." *Missouri Housing Development Comm'n v. Brice*, 919 F.2d 1306, 1315 (8th Cir. 1990); *accord Mendota Ins. Co. v. Hurst*, 965 F. Supp. 1282, 1286-87 (W.D. Mo. 1997).

SOF ¶ 49 – The phrase "medically therapeutic," as describing the anxiety-reducing purpose of Valium, is supported by page 40 of Defendant Lombardi's deposition. *See* Plaintiffs' Ex. 1 (also Defendants' Ex. 7) (Lombardi Depo.), at 40 (Question: "And so that is the

therapeutic or medical purpose for the use of that particular medication?" Answer: "I think that's correct.").

SOF ¶ 60 – Defendants again rely on M3's hearsay statement that one of the non-medical personnel has medical experience in his past, apparently in the Army. *See* ECF Doc. 242, at 11. This contention is ineffectual for the reasons explained with respect to SOF ¶ 13, above.

SOF ¶ 63 – The testimony cited by Defendants does not contradict the evidence that it was a non-medical person who initially *taught* NM1 and NM2 how to administer the lethal injection drugs, as opposed to M3's role in watching NM1 and NM2 during *subsequent* rehearsal-executions.

SOF ¶ 66 – Defendants' attempt to controvert SOF 66 is unavailing. Anesthesiologist M3 testified that intramuscular injection of thiopental would cause burning. Plaintiffs' Ex. 5 (also Defendants' Ex. 2) (M3 Depo.), at 40. He also testified that there exists a risk that improper administration of thiopental could cause rupturing of the vein. *Id.* at 126, 159. Because veins are surrounded by muscle tissue, one may readily infer that thiopental injected into a ruptured vein would go into the prisoner's muscle tissue, and thus, would cause burning as with other intramuscular injections of the same drug. Defendants offer no evidence to contradict this straightforward inference from M3's testimony. Furthermore, if the vein is ruptured, then the thiopental would not be injected into the prisoner's circulatory system, where the drug produces its sedating effect to the degree intended. *See* Plaintiffs' Opposition Ex. D (Heath Affidavit), at 5-6 (stating that the risk of infiltration, caused by the non-medical administration of thiopental, creates "a gratuitous and substantial risk that anesthetic depth will be inadequate and that the execution will be agonizing").

SOF ¶¶ 77-78 – Defendants do not cite or present any evidence to substantiate the

claimed rehearsal-execution in January, and have also failed to disclose any such supporting evidence through ongoing discovery as required by Rule 26(e). Therefore, Plaintiffs' statements 77 and 78 must be taken as true for purposes of summary judgment. *See* Local Rule 56.1(a); *United States v. United States Currency in the Amount of $15,426.00*, No. 06-0862-CV-W-FJG, 2008 WL 4816984, at *1 n.1 (W.D. Mo. Oct. 31, 2008); *Lewis v. Police Officer Vidal*, No. 06-00036-CV-W-SWH, 2007 WL 2422877, at *3 n.14 (W.D. Mo. Aug. 21, 2007).

SOF ¶ 81 – Defendants' averment that anesthesiologist M3 does not write anesthesia prescriptions because the drug is either administered by himself or "someone" under his direct control is misleading. *See* ECF Doc. 242, at 13. In his medical practice, M3 does not allow just any "someone" to administer anesthesia under his supervision. Rather, the anesthesia is always administered by M3 or another anesthesia specialist. *See* Plaintiffs' Ex. 5 (also Defendants' Ex. 2) (M3 Depo.), at 81, 123.

REPLY ARGUMENT

I. Defendants misstate the presumption against implied preemption, which does not displace the need to determine whether it is "impossible" to comply with both federal law and state law or practice, and also whether the state law or practice stands as an "obstacle" to federal statutory objectives.

Defendants newly rely on *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), to argue that the Court must presume that Congress did not intend to preempt an area traditionally regulated by the states. *See* Suggestions in Opposition to Plaintiffs' Motion for Summary Judgment (ECF Doc. 242), at 23-24; Reply Suggestions in Support of Defendants' Motion for Summary Judgment (ECF Doc. 243), at 5-6. Defendants correctly state the premise of *Wyeth* – a suit involving the preemptive effect of the FDCA on state tort law remedies. But they ignore the Supreme Court's preemption analysis even under the presumption invoked here.

In *Wyeth*, the plaintiff suffered gangrene and eventually required the amputation of her arm because of the anti-nausea drug Phenergan. The drug was administered by the risky "IV-push" method – interestingly enough, the same method through which non-medical personnel inject sodium thiopental in this case – rather than the comparatively safer "IV-drip" method, in which the drug is diluted into a saline solution and then dripped into the patient's vein through a catheter. Plaintiff Levine alleged, and the jury found, that the drug's labeling was inadequate because it failed to warn medical practitioners against using the "IV-push" method. *See* 129 S. Ct. at 1191-93. The Supreme Court held that Levine's state law failure-to-warn claim was not preempted by the FDCA, even though the FDA had approved the drug's label. *Id.* at 1196-1204. True, the Supreme Court stated the longstanding principle that, in traditionally state-regulated areas, a court assumes "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 1194-95, quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (itself quoting *Rice v. Santa Fe*

Elevator Corp., 331 U.S. 218, 230 (1947)). But neither *Wyeth* nor any other authority requires an ***express*** preemptive purpose in order for Congress's intent to be "clear and manifest." *See Farina v. Nokia, Inc.*, 625 F.3d 97, 130 (3rd Cir. 2010) (noting that *Wyeth* does not support "the proposition that conflict preemption should not be found absent an express preemption provision").

Even in *Wyeth* itself, the Supreme Court undertook an exacting analysis of whether it was impossible for the Wyeth to comply with both state and federal law, and also whether state tort law frustrated the FDCA's purposes. *See* 129 S. Ct. at 1196-1203. On the first question, the Court held that Wyeth could have complied with both the FDCA's warning label requirements *and* state law warning obligations: the company could have strengthened its warning about "IV-push" administration without the FDA's approval of an enhanced label. *Wyeth*, 129 S. Ct. at 1196-99. On the second question, the Court observed that tort suits such as Levine's did not pose an obstacle to congressional objectives. Congress established a floor safety regulations, and not a ceiling. Thus, it was permissible for states to impose consumer-protection requirements above the minimum established by the FDCA. *Id.* at 1199-1203. As evidence of congressional purposes, the Supreme Court relied on the fact that state tort suits had operated for decades as a supplementary form of regulation, and without congressional disapproval. *Id.* at 1200; *but see Farina*, 625 F.3d at 130 (noting that this holding does not supplant the need for conflict preemption).

Nothing in Plaintiffs' claims is remotely in tension with *Wyeth*. First, *Wyeth* is a case about implied preemption and has no bearing in matters of express preemption, including the express preemption provision of the Controlled Substances Act. *See* 21 U.S.C. § 903; *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1205 (8th Cir.

2010); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 783 (D. Minn. 2009). Second, even under implied preemption, it is physically "impossible" for someone to comply with both the FDCA *and* Defendants' method of execution.[2] The FDCA requires the issuance of a valid medical prescription for the dispensing of regulated "drugs," *see* 21 U.S.C. § 353(b)(1), and yet, Defendants' procedures make no allowance or provision for a medical practitioner to issue a prescription that accords with the practitioner's clinical judgment of how best to alleviate the prisoner's pain. *See* Plaintiffs' SOF ¶¶ 56, 57 (both uncontroverted).

Third, Defendants' method stands as an obstacle to the "core" congressional purpose of ensuring that a "drug" is "safe and effective for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *United States v. Lane Labs-USA*, 324 F. Supp. 2d 547, 563 (D.N.J. 2004). That purpose is served by the participation of medical professionals, as the Court has recognized. *See* Order of March 2, 2010 (ECF Doc. 72), at 17-18. This is not a case, such as *Wyeth*, in which the state law supplements federal regulation, thus requiring a court to assess whether Congress intended for its statute to serve as both a floor and a ceiling for regulated conduct. *See Wyeth*, 129 S.Ct. at 1199-1202; *accord Lefaivre v. KV Pharmaceutical Co.*, — F.3d —, No. 10-1326, 2011 WL 148730, at *5 (8th Cir. Jan. 19, 2011) (state law claims not an obstacle to congressional purposes because "state law is complementary to federal drug regulation"). Far from serving as an additional "layer of consumer protection," *Wyeth*, 129 S. Ct. at 1202, the State conduct in this case is directly contrary to the protections of federal law. *See* Order of March 2, 2010 (Doc. 72), at 9-10 ("If the statutes apply to lethal injection, ignoring those safeguards, as Plaintiffs allege Defendants intend to do, places Plaintiffs at risk.").

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[2]Defendants do not dispute Plaintiffs' showing that the execution protocol, either as written or as consistently implemented, is subject to preemption even though it is not a statute or regulation. *See* Suggestions in Support of Plaintiffs' Motion for Summary Judgment (ECF Doc. 210), at 17-18.

II. Defendants wrongly discount the difference between a preemption suit and an enforcement suit, and preemption is established here by the undisputed facts on summary judgment.

Defendants' many arguments bear a common thread: without explaining why, Defendants reject the distinction between (a) a plaintiff's suit to enforce some federal right when the federal statute does not confer a private cause of action, and (b) a private citizen's suit to establish that the conduct or policy of state actors is preempted by some federal law that does not confer a right of action. *See* Order of Aug. 19, 2010 (ECF Doc. 138), at 3-11 (examining both frameworks). But this issue is settled by this Court's prior order. The only issue before the Court now is whether plaintiffs have established preemption as a matter of law. This Court may, therefore, discount the bulk of the defendants' arguments in opposition to plaintiffs' motion for summary judgment.

On the issue of standing, for example, Defendants argue that Plaintiffs lack a "legally protected interest" in being executed any particular way. *See* Opposition to Plaintiffs' Motion for Summary Judgment (ECF Doc. 242), at 29; Reply in Support of Defendants' Motion for Summary Judgment (ECF Doc. 243), at 1-2. On the merits, Defendants believe they are entitled to judgment under various court decisions issued after this Court's denial of dismissal in March, even though none of those decisions squarely addresses whether a prisoner may advance a preemption suit under the FDCA and CSA. *See* ECF Doc. 242, at 15-17. Defendants believe that the preemption theory is no more than a "magical formula" that doesn't change the nature of the prisoner's claims. ECF Doc. 242, at 15-16; ECF Doc. 243, at 2-3. Similarly, Defendants believe they are entitled to sovereign immunity based upon the FDCA's provision that only the federal government may sue to "enforce" the statute's requirements. ECF Doc. 242, at 21; ECF Doc. 243, at 4. A recurring theme, then, is Defendants' unexplained disagreement with the

Court's order of August 19.

A few illustrations of private preemption suits may help to clarify the matter. The Court is already familiar with *Planned Parenthood of Houston & Southeast Texas v. Sanchez*, 403 F.3d 324 (5th Cir. 2005); *see* ECF Doc. 138, at 8-9. In that case, Planned Parenthood and others challenged a Texas statute barring the distribution of federal family planning funds to organizations that perform abortions. Plaintiffs argued that the statute was preempted by Public Health Service Act and the Social Security Act, under which the state received the funds in question. Neither statute conferred a private right of action on funded organizations like Planned Parenthood, but nevertheless, the Fifth Circuit held that the plaintiffs could proceed with a preemption suit under the Supremacy Clause. *See* 403 F.3d at 331-34. The State Department of Health argued, as Defendants do here, that it was entitled to dismissal, because plaintiffs were not seeking to vindicate any particular federal "right" or to enforce any particular statutory "duty." The Fifth Circuit disagreed, explaining that a preemption suit against state actors does not require a statutory right of action. *Id.* The question posed "little difficulty." *Id.* at 335. The Court remanded the case for further consideration, concluding that state and federal law could probably be harmonized so as to defeat a preemption claim. *Id.* at 342-43 (examining burdens of forcing grant recipients to create non-abortion affiliates).

To similar effect is the Tenth Circuit's opinion in *Qwest v. City of Santa Fe*, 380 F.3d 1258 (10th Cir. 2004). The Tenth Circuit held that certain provisions of the Telecommunications Act preempted a local ordinance establishing requirements for telecom companies to access city-owned rights of way. The court determined that Qwest lacked a right of action under the TCA and could not proceed under 42 U.S.C. § 1983. *Id.* at 1265-67. Nevertheless, the company had an implied right of action under the Supremacy Clause:

> A claim under the Supremacy Clause simply asserts that a federal statute has taken away local authority to regulate a certain activity. In contrast, an implied private right of action is a means of enforcing the substantive provisions of a federal law.

Id. at 1266 (quotation omitted).

Similar analysis governed the Eight Circuit's opinion in *Wright Electric v. Minnesota State Board of Electricity*, 322 F.3d 1025 (8th Cir. 2003). An electrical company challenged a state statute and regulation requiring that unlicensed electricians be supervised by licensed electricians at certain worksites, and that each such licensed electrician could supervise only two unlicensed ones. State officials cited the company because its apprenticeship program violated the statute and regulation, but Wright argued that these enactments were preempted by ERISA. In considering that claim, the court did not require Wright to show that its apprenticeship program was an "ERISA plan," so that Wright could enforce its plan under the statute. The court instead ruled that the company could proceed with a preemption suit under the Supremacy Clause, regardless of any statutory right of action. The Eighth Circuit easily grasped the distinction between the two types of suits: "Wright Electric is not seeking enforcement of ERISA or plan terms. Rather, it is seeking to bar enforcement of a state statute," it explained. "In other words, a claim under the Supremacy Clause that a federal law preempts a state regulation is distinct from a claim for enforcement of that federal law." *Id.* at 1029.

Authorities such as *Planned Parenthood*, *Qwest*, and *Wright Electric* dispose of many of the arguments Defendants raise here. Plaintiffs have standing even if they lack a "legally protected interest" to enforce the FDCA and CSA; aside from showing an injury-in-fact, it suffices that the preemption claim is itself "not wholly insubstantial or frivolous." *Qwest*, 380 F.3d at 1264; *accord Burgio and Campofelice, Inc. v. New York State Dept. of Labor*, 107 F.3d 1000, 1005 (2nd Cir. 1997) ("Burgio clearly has standing in the ordinary sense, as that term has

been defined by the Supreme Court. By complaining that the State has wrongfully caused the withholding of a significant sum of money owed to Burgio pursuant to a statute preempted by federal law, Burgio has alleged a concrete and immediate injury, caused by defendants, which is likely to be redressed by favorable action in this court."). Moreover, a preemption claim rests upon considerably more than some formalistic "magical formula" of language in a plaintiff's complaint. *See* ECF Doc. 243, at 2-3. A preemption claim lies because a plaintiff has a cognizable claim against state parties whose injurious activities conflict with federal law, even if the plaintiff cannot sue private parties who violate the same law. It is an independent cause of action, not, as defendants would have it, a semantic end-run around the plaintiff's lack of a cause of action. The Supremacy Clause, after all, makes federal law superior to state practice, not private practice. "Preemption concerns the federal structure of the Nation rather than the securing of rights, privileges and immunities to individuals." *Lankford v. Sherman*, 451 F.3d 496, 509 (8th Cir. 2006), quoting *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103, 117 (1989). That is why Defendants are not assisted by the numerous cases holding that prisoners lack a private right of action under the FDCA and CSA, such as *Durr v. Strickland*, No. 2:10-cv-288, 2010 WL 1610592 (S.D. Ohio Apr. 15, 2010). Those decisions support the Court's partial grant of judgment on the pleadings, but they do not conflict with the Court's allowance of Plaintiffs' preemption claim. *See* Order of Aug. 19, 2010 (ECF Doc. 138), at 7-11. Defendants also miss the mark in arguing that only the federal government may "enforce" the FDCA, for a "claim under the Supremacy Clause that a federal law preempts a state regulation is distinct from a claim for enforcement of that federal law." *Wright Electric*, 322 F.3d at 1028.

The State's position is particularly weak under the Controlled Substances Act. In denying judgment on the pleadings, the Court observed that Defendants had not pointed to any source of

law ousting private preemption claims. ECF Doc. 138, at 10. That failure remains to this date. Indeed, the CSA expressly provides for preemption of state law when there is a "positive conflict" and the two "cannot consistently stand together." 21 U.S.C. § 903. Such a conflict plainly exists in this case; it is impossible for the Defendants to comply with their protocol and policies *and* the CSA. Among other "positive conflicts," the Defendants' unbending procedure is to have unlicensed non-medical personnel actually administer the Schedule III controlled substance sodium thiopental, and yet, the CSA forbids the "dispensing" of this drug other than by someone who possesses a valid registration with the Attorney General – or at least by a practitioner who is being supervised by such a registrant and is himself or herself professionally authorized to administer the controlled substance under state law. *See* Plaintiffs' SOF ¶¶ 26-29, 58-59 (all uncontroverted); 21 U.S.C. § 822(a)(2); 21 U.S.C. § 802(10) (stating that the term "dispense" includes the "administering of a controlled substance"); Drug Enforcement Administration, Office of Diversion Control, *Practitioner's Manual: An Informational Outline of the Controlled Substances Act* (2006) (available at http://www.deadiversion.usdoj.gov/pubs/ manuals/pract/ pract_ manual 012508.pdf), at 28 (supervisee-practitioner may administer controlled substances "to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices").[3]

[3]As previously explained, Missouri law does not permit anesthesia to be administered by anyone other than an anesthesiologist, a nurse anesthetist, or a licensed anesthesiologist assistant (other than in veterinary and dental procedures). *See* Mo. Rev. Stat. §§ 334.104.2, 334.104.7, 334.402.1, 334.424.1; 20 Mo. CSR §§ 2150-9.040, 2200-4.200.3(G)(9).

III. Defendants' cramped reading of the CSA and FDCA is unsustainable.

Defendants again argue that their conduct is consistent with federal law. *See* Suggestions in Opposition to Plaintiffs' Motion for Summary Judgment (ECF Doc. 242), at 24-28; Reply Suggestions in Support of Defendants' Motion for Summary Judgment (ECF Doc. 243), at 4-5. They are wrong for the reasons explained below.

A. The CSA is violated when controlled substances are dispensed or administered in a manner that conflicts with prevailing medical practice, irrespective of whether the violation involves "drug abuse" or the "drug trade."

Citing *Gonzales v. Ashcroft*, 546 U.S. 243 (2006), Defendants argue that the CSA is intended only to prohibit "drug abuse," and that the prescription-related activities of physicians do not violate the Act unless they implicate this concern. ECF Doc. 242, at 24-25. ***But the Eighth Circuit has already rejected Defendants' reading of Gonzales***. *See United States v. Kanner*, 603 F.3d 530, 533-35 (8th Cir. 2010), and authorities cited; *United States v. Lovern*, 590 F.3d 1095, 1097-1100 (10th Cir. 2009). *Kanner* and *Lovern* were "internet pharmacy" cases in which physicians violated the FDCA by issuing prescriptions based on a patient's electronic questionnaire, and without actually seeing or examining the patient – conduct that undoubtedly endangers patients' health. Both courts squarely rejected the view that *Gonzales* limits CSA violations to those which involve "illicit drug dealing and trafficking as conventionally understood." *Kanner*, 603 F.3d at 533-34; *Lovern*, 590 F.3d at 1100. It sufficed, for Kanner's conviction, that he dispensed prescription drugs outside the scope of accepted medical practice. *See* 603 F.3d at 534-35; *accord United States v. Smith*, 573 F.3d 639, 646-49 (8th Cir. 2009) (upholding jury instruction that prescription must issue in "the usual course of professional practice," in the sense that the practitioner "has acted in accordance with a standard of medical practice generally recognized and accepted in the United States");

Anesthesiologist M3 and his colleagues dispense prescription drugs in a manner that similarly violates the accepted practice of medicine. M3 does not issue a prescription for the Schedule III controlled substance sodium thiopental, even though the drug is administered for the therapeutic purpose of alleviating pain, and even though he does not directly administer it himself. *See* 21 U.S.C. § 829(b). Likewise, M3 relies on unregistered, unlicensed, and otherwise unqualified non-medical employees to administer the anesthetic, which violates the CSA and state law alike. *See* Plaintiffs' SOF ¶¶ 13, 26-28, 58-61; 21 U.S.C. § 822(a)(2) ("[e]very person who dispenses . . . any controlled substance shall obtain from the Attorney General a registration"); 21 U.S.C. § 802(10) ("dispense" includes "the administering of a controlled substance"); Drug Enforcement Administration, Office of Diversion Control, *Practitioner's Manual: An Informational Outline of the Controlled Substances Act* (2006) (available at http://www.deadiversion.usdoj.gov/pubs/ manuals/pract/pract_ manual 012508.pdf), at 28 (stating that a "practitioner" who is an agent or employee of a DEA-registered practitioner may rely on his or her superior's registration to administer controlled substances "to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices"); Mo. Rev. Stat. §§ 334.104.2, 334.104.7, 334.402.1, 334.424.1; 20 Mo. CSR §§ 2200-4.200.3(G)(.9). In the usual course of his practice, M3 would never delegate the administration of anesthesia to the likes of non-medical syringe-pushers NM1 and NM2. *See* Plaintiffs' Ex. 5 (M3 Depo.) (also Defendants' Ex. 2), at 81, 123.

B. The FDCA's requirement that dangerous drugs "shall" be dispensed only upon prescription is not limited to pharmacists.

In relevant part, the FDCA requires that a "drug," which is unsafe for use without medical supervision, "shall be dispensed only" upon a valid prescription issued by a medical practitioner who is "licensed by law to administer such drug." 21 U.S.C. § 353(b)(1). The FDCA exists to

ensure that such "drugs" are "safe and effective" for their intended medical use. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Defendants nevertheless argue that the prescription requirement of section 353(b)(1) targets pharmacists who dispense prescription drugs over-the-counter, and not physicians who dispense such drugs without a prescription. *See* ECF Doc. 242, at 26-27.

Once again, the courts have long since rejected Defendants' argument. In *Brown v. United States*, 250 F.2d 745 (5th Cir. 1958), the Fifth Circuit upheld the conviction of a physician for dispensing harmful drugs without a prescription. It specifically rejected Brown's argument that the FDCA does not apply to physicians, and it noted the statute's broad language that the relevant drugs "*shall* be dispensed" only upon a prescription. *Id.* at 746. The court also observed that a similar FDCA conviction was overseen by no less an authority than Charles Evans Whittaker himself, when he was a member of this Court. *Id.* Then-Judge Whittaker observed as follows when sentencing a physician on a no-contest plea:

> Now, there seems to be some concept among the members of the medical profession that to have a license to deal in medicine carries a license to deal in barbiturates. That is not the law. The medical profession might just as well understand it. If I come to you for treatment and you, in your medical capacity examine me, and after examination determine that certain barbiturates would be beneficial to me, then you have a right to write a prescription to me, and then I have a right to get them and use them, but not otherwise.

Id., quoting transcript from *United States v. Amin Boutros*, (W.D. Mo. Case No. 19,304-CR), Dec. 23, 1955. Courts continue to recognize that the FDCA applies to physicians as fully as it does to pharmacists, or to anyone else who dispenses prescription drugs without a prescription. *E.g.*, *United States v. Smith*, 573 F.3d 639, 650-52 (8th Cir. 2009); *id.* at 646 (noting conviction of doctor who conspired with businessman Smith); *United States v. Nazir,* 211 F. Supp. 2d 1372, 1374-75 (S.D. Fla. 2002). Defendants' contrary reading of the statute is unsupportable.

IV. Plaintiffs have standing because Defendants' non-compliance with the FDCA and CSA creates medical risks that compliance would alleviate.

Defendants argue that Plaintiffs cannot show an "injury in fact" and that they lack a "legally protected interest" against being executed in the manner of Defendants' choosing. *See* Defendants' Suggestions in Opposition to Plaintiffs' Motion for Summary Judgment (ECF Doc. 242), at 28-32; Reply Suggestions in Support of Defendants' Motion for Summary Judgment (ECF Doc. 243), at 1-2. Both arguments are unavailing.

A. Missouri's counter-statutory method of execution places Plaintiffs at risk.

To establish standing, Plaintiffs need not show that they will certainly, or even probably, suffer pain as a result of Defendants' statutory violations; it suffices to show a risk of injury or suffering. A plaintiff must "show that he personally has suffered some actual ***or threatened*** injury as a result of the putatively illegal conduct of the defendant." *Valley Forge Christian College v. Americans United for Separation of Church and State*, 454 U.S. 464, 472 (1982) (emphasis added). In *Massachusetts v. EPA*, 549 U.S. 497 (2007), for example, the Commonwealth had standing to challenge the EPA's failure to regulate new motor vehicle emissions. The viable "injury in fact" was that such emissions contribute to global warming, which, in turn, threatens coastal areas because of rising sea levels: "The risk of catastrophic harm, though remote, is nevertheless real. That risk would be reduced to some extent if petitioners received the relief they seek." *Id.* at 526; *accord Missouri Coalition for Environment v. Federal Energy Reg. Comm'n*, 544 F.3d 955, 957 (8th Cir. 2008) (lack of environmental impact statement for hydroelectric power plant created injury in fact, specifically, "the increased risk of environmental harm stemming from ill-informed decision-making"). Perhaps the clearest illustration of Plaintiffs' standing is *Dimarzo v. Cahill*, 575 F.2d 15 (1st Cir. 1978). There, the inmates of a county jail alleged that they were subjected to an unconstitutionally high risk of fire

due to flammable floor coverings and mattresses, inadequate fire hoses, and individually locked cells. *Id.* at 16. The inmates had standing: "One need not wait for the conflagration before concluding that a real and present threat exists." *Id.* at 18.

1. ***The lay "IV Push" problem*** – Defendants use non-medical personnel to conduct an "IV push" of sodium thiopental, which, as Plaintiffs have explained, violates the CSA and FDCA. *See* Suggestions in Support of Plaintiffs' Motion for Summary Judgment (ECF Doc. 210), at 22-24. Defendants themselves acknowledge the risk that an improper "IV push" may cause the prisoner's vein to rupture, which could lead to severe pain as well as ineffectual sedation as the thiopental would enter muscle tissue rather than the prisoner's bloodstream. Plaintiffs' Ex. 5 (M3 Depo.) (also Defendants' Ex. 2), at 40-41, 126, 159; Plaintiffs' Ex. 21 ("Training Academy Lesson Plan"), at 11. It is notable that anesthesiologist M3 never relies on non-medical personnel to administer anesthesia in his medical practice; he relies solely on anesthesia specialists, as state law requires him to. Plaintiffs' Ex. 5 (M3 Depo.) (also Defendants' Ex. 2), at 81, 123; Mo. Rev. Stat. §§ 334.104.2, 334.104.7, 334.402.1, 334.424.1; 20 Mo. CSR §§ 2200-4.200.(3)(G)(.9). The medical profession, then, recognizes that it is unreasonably risky for laypersons to administer anesthesia. That risk would be eliminated if the thiopental were administered by M3 or another suitably qualified practitioner.

The observations of anesthesiologist and professor Mark J.S. Heath, M.D., confirm that Plaintiffs are placed at dangerous and unnecessary risk from the non-medical administration of thiopental. *See* Plaintiffs' Opposition Exhibit D, at 5-6 (affidavit). Dr. Heath opines that a lay person lacks the experience and qualifications needed to gauge and act upon the varying degree of "back-pressure" sensed by an anesthesia specialist while injecting a syringe. *Id.* at 5. That skill is necessary in order to determine when an anesthetic such as thiopental is being pushed into

the patient's circulatory system through the vein, as opposed to infiltrating the surrounding tissue. *Id.* Dr. Heath states that proper administration requires a grasp of medical subtlety that is simply unavailable to non-medical personnel:

> [D]etection of infiltration relies in part on perceiving a gradually accruing resistance to injection, and this subtlety would be lost on a person who lacked the requisite experience. No amount of "rehearsal" during simulated executions can substitute for the ineffable experience that is garnered from clinical practice.

Id. Non-medical personnel, then, may be injecting the anesthetic into muscle tissue without even knowing it. *Id.*

Dr. Heath also believes it medically unacceptable for Defendants to rely on a "generic" instruction of dosing the thiopental at a rate of 1 cc per second. *Id.* Clinical practice forbids the use of such "one size fits all" injection rates, because a qualified anesthesia specialist must customize the flow to account for such factors as "the size of the IV catheter and the geometry of its situation in the vein[,] and the attributes of the veins that are receiving the drug." *Id.* All told, the lay administration of sodium thiopental creates a "gratuitous and substantial risk that anesthetic depth will be inadequate and that the execution will be agonizing." *Id.* at 6. The defendants have not controverted Dr. Heath's opinions with expert or other evidence.

2. ***The non-prescription problem*** – Plaintiffs are likewise imperiled by the absence of a medical prescription. A prescription represents a medical doctor's independent professional judgment that a particular drug, administered in a particular way, is suitable to treat a particular malady or prevent a particular risk. But M3 exercises no such judgment. *See* Plaintiffs' Ex. 5 (M3 Depo.) (also Defendants' Ex. 2), at 39 ("There's other things that can be used that are better drugs, but they're not part of the protocol that is used now."), 134. Moreover, Defendants are simply wrong in characterizing a prescription as a mere piece of paper. *See* Doc. 242, at 31 ("A prescription does not make the process safer . . ."). Before M3 could write a medically

acceptable prescription for sodium thiopental or Valium, he would have to make a medical judgment that these drugs would be optimal for minimizing the risk of pain. Dr. Heath agrees that the inability of anesthesiologist M3 to exercise his independent medical judgment presents "a gratuitous and substantial risk of a cruel execution." Plaintiffs' Opposition Exhibit D, at 6. Defendants' procedures deviate from established medical practice, in which "M3 is surely at liberty to customize his technique to best ensure the establishment and maintenance of the desired anesthetic depth." *Id.*

Defendants point out that, in the *Taylor* litigation, Dr. Heath criticized the State for *not* having a protocol that overrode the physician's discretion. *See* ECF Doc. 243, at 2. But Defendants disingenuously ignore the context of the earlier litigation. Dr. John Doe No. 1 was dyslexic, had difficulty reading the drug dosages, and varied the amount of anesthesia he administered from execution to execution. *Taylor v. Crawford*, 487 F.3d 1072, 1075 (8th Cir. 2007). Thus, the prisoners justifiably argued that the State needed a protocol. Surely the issue of *having* a protocol is distinct from the issue of whether the protocol ought to accord with the physician's medical judgment of how best to alleviate the risk of excruciating pain – either because the physician conscientiously prescribes the drugs required by the protocol, or if that is not possible, because the protocol entails drugs consistent with the physician's clinical judgment.

B. Standing does not require a constitutional or statutory "right" to be executed in accordance with federal statutes.

Defendants insist that the prisoners do not have a "legally protected interest" in being executed by a physician, much less by a physician who obeys the law. ECF Doc. 242, at 29; ECF Doc. 243, at 1-2. The State's argument is fallacious in numerous respects. First, Defendants conflate Article III standing with the merits of Plaintiffs' claims. The two inquiries are distinct. *Warth v. Seldin*, 422 U.S. 490, 500 (1975); *McCarney v. Ford Motor Co.*, 657 F.2d 230, 232-33

(8th Cir. 1981). Plaintiffs do not need a "protected interest" in the form of a private right of action under the FDCA and CSA. If that were the law, then no private plaintiff would ever have Article III standing to bring a preemption suit. *But see* Order of Aug. 19, 2010 (ECF Doc. 138), at 8-10, and cases cited ("Courts have repeatedly entertained federal preemption claims seeking declaratory and injunctive relief even where the statutes at issue do not grant a private right of action."); *Shaw v. Delta Air Lines*, 463 U.S. 85, 96 (1983) ("A plaintiff who seeks injunctive relief from state regulation, on the ground that such regulation is pre-empted by a federal statute which, by virtue of the Supremacy Clause of the Constitution, must prevail, thus presents a federal question which the federal courts have jurisdiction under 28 U.S.C. § 1331 to resolve.").

Defendants compound their error by relying on precedent involving the Eighth Amendment, specifically, *Taylor v. Crawford*, 487 F.3d 1072 (8th Cir. 2007). *See* ECF Doc. 243, at 1-2. *Taylor* does not bear upon whether Defendants must comply with the FDCA and CSA, which were not at issue. Neither does it assist Defendants to erect, and then attack, the overarching strawman proposition that "an execution must follow the same procedure as a clinical surgery." ECF Doc. 243, at 2. It is, after all, *the State* that has chosen to administer a Schedule III controlled substance as the first of three execution drugs. It is the State that convinced the Eighth Circuit, and this Court, that its execution procedures are "humane" because that drug, as administered, sedates the prisoner. *See* Order of March 2, 2010, (ECF Doc. 72), at 16-18. And it is precisely because the State administers a controlled substance, for an avowedly medical purpose, that the State is subject to the same laws that apply to anyone else who administers the same drug for the same purpose. *See* U.S. Const. art. VI cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land.").

V. Plaintiffs' suit does not seek to "enforce" the FDCA and CSA, and none of the authorities cited by Defendants involve a preemption suit under these statutes.

Defendants reiterate previous arguments that this suit impermissibly "enforces" statutes that are enforceable only by the federal government. *See* Suggestions in Opposition to Plaintiffs' Motion for Summary Judgment (ECF Doc. 242), at 15-16. Defendants offer several cases in support: *Durr v. Strickland*, No. 2:10-cv-288, 2010 WL 1610592 (S.D. Ohio Apr. 15, 2010), *aff'd* 602 F.3d 788 (6th Cir. 2010); *Jones v. Hobbs*, — F. Supp. 2d —, No. 5:10CV00065 JLH, 2010 WL 2985502 (E.D. Ark. July 26, 2010); *Bowling v. Haas*, No. 3:07-032-KKC, 2010 WL 3825467 (E.D. Ky. Sept. 23, 2010); *West v. Ray*, No. 3:10-0778, 2010 WL 3825672 (M.D. Tenn. Sept. 24, 2010); and *Brown v. Vail*, 237 P.3d 263 (Wash. 2010).

These cases do not contradict this Court's ruling that Plaintiffs may proceed on a preemption theory under the Supremacy Clause even if the FDCA and CSA do not confer a private right of action. *See* Order of Aug. 19, 2010 (ECF Doc. 138), at 7-11. Neither do they implicate the "open question" described in the Court's order of August 19. *See id.* at 11. Defendants' arguments about these cases do not materially differ from those in their motion for summary judgment. *See* ECF Doc. 213, at 16-18. Plaintiffs therefore incorporate their previous analysis in opposing Defendants' motion. *See* Plaintiffs' Suggestions in Opposition to Defendants' Motion for Summary Judgment (ECF Doc. 226), at 16-19.

VI. The "plain statement" rule does not obviate Defendants' duty to comply with federal law when carrying out executions.

Again, Defendants' arguments are identical to those advanced in their own motion for summary judgment. *See* ECF Doc. 213, at 18-20. Plaintiffs again incorporate their analysis from the opposition to Defendants' motion. *See* Plaintiffs' Suggestions in Opposition to Defendants' Motion for Summary Judgment (ECF Doc. 226), at 20-24.

VII. Because the CSA and FDCA do not preclude private preemption suits against state actors, Defendants are not immune from suit under the Eleventh Amendment.

Defendants argue that the CSA and FDCA effectively forbid private preemption actions, so that the Eleventh Amendment bars the suit. *See* ECF Doc. 242, at 19-22. Once more, the argument is identical to that advanced in Defendants' motion for summary judgment. Plaintiffs therefore incorporate the relevant portion of their suggestions in opposition to Defendants' motion for summary judgment. *See* ECF Doc. 226, at 25-27.

CONCLUSION

WHEREFORE, for the foregoing reasons, Plaintiffs respectfully renew their request that the Court grant Plaintiffs' motion for summary judgment, deny Defendants' motion for summary judgment, and afford such further relief as law and justice require, including appropriate injunctive remedies forbidding Defendants from carrying out executions in conflict with federal law.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was forwarded for transmission via Electronic Case Filing (ECF) this 24th day of February, 2011, to Andrew W. Hassell, Michael J. Spillane, and Stephen D. Hawke, Office of the Attorney General, P.O. Box 899, Jefferson City, Missouri 65101.

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